K111619

JUL - 6 2011

## 510(k) Summary

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|---|---|
| Trade Name: | Modified Concentric Microcatheter |
| Common Name: | Diagnostic Intravascular Catheter |
| Classification Name: | Diagnostic Intravascular Catheter, 21CFR 870.1200 – Class II |


Submitter

Concentric® Medical, Inc.
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Facility Registration #2954917

Contact: Kirsten Valley, Senior Vice President, Technology and Regulatory Affairs


Predicate Device: Concentric Microcatheter (K091961)

### Device Description

The Modified Concentric Microcatheter is a single lumen, braided, variable stiffness catheter designed for use in the selective placement of fluids and/or other devices or agents into the peripheral, coronary and neuro vasculature during diagnostic and/or therapeutic procedures. A luer hub on the proximal end of the shaft enables connection to the rotating hemostasis valve included in the package. The radiopaque shaft and distal marker facilitate fluoroscopic visualization. The catheter shaft is coated with a hydrophilic coating to reduce friction during use.

### Intended Use

The Modified Concentric Microcatheter is indicated for use in the selective placement of fluids and/or other devices or agents into the peripheral, coronary and neuro vasculature during diagnostic and/or therapeutic procedures.

### Technological Characteristics

The Modified Concentric Microcatheter has the same technological characteristics as the K091961 predicate device. The device design, materials used, function, physical properties and composition have not been changed.

### Testing Summary

The results of verification and validation conducted on the Modified Concentric Microcatheter demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate device. Specifically, the following tests were performed:

- Kink Resistance – the device's ability to withstand kinking when flexed was successfully evaluated.
- Leak Resistance – the device's leak resistance when subjected to both high pressure and vacuum was successfully evaluated.
- Flexibility Testing – the device's ability to navigate tight bends was successfully evaluated.
- Flow Testing – the device's ability to infuse fluids was succesfully evaluated.
- Tensile Testing – the device's mechanical integrity under tensile loads was successfully evaluated.
- Torque Testing – the device's mechanical integrity when subjected to torsion was successfully evaluated.

The materials on the Modified Concentric Microcatheter are the same as the predicate device. As a result, the following biocompatibility tests were leveraged.

- Hemocompatibilty/Coagulation
- Cytotoxicity
- Systemic Toxicity
- Hemocompatibility/Hematology
- Sensitization
- Irritation/Intracutaneous Reactivity
- Pyrogen/Sytem.Toxicity

## Summary of Substantial Equivalence

The Modified Concentric Microcatheter is substantially equivalent to the predicate device with regard to device design, intended use, and patient population. The results of verification and validation conducted on the Modified Concentric Microcatheter demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL - 6 2011

Concentric Medical, Inc.
c/o Ms. Kristen Valley
Senior Vice President, Technology and Regulatory Affairs
301 E. Evelyn Avenue
Mountain View, CA 94041

Re: K111619
Trade/Device Name: Modified Concentric Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Catheter, Intravascular, Diagnostic
Regulatory Class: Class II
Product Code: DQO
Dated: June 9, 2011
Received: June 10, 2011

Dear Ms. Valley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Statement of Indications for Use

INDICATIONS FOR USE

| | |
|---|---|
| 510(k) Number (if known): | This application K111619 |
| Device Name: | Modified Concentric Microcatheter |
| Indications for Use: | The Modified Concentric Microcatheter is indicated for use in the selective placement of fluids and/or other devices or agents into the peripheral, coronary and neuro vasculature during diagnostic and/or therapeutic procedures. |

Prescription Use _X_ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _X_ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K111619